

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 77029**

Issued To:

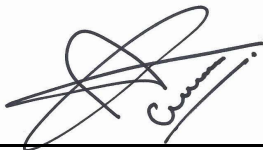
**Kardinero Medikal Sistemler Sanayi ve
Ticaret Anonim Sirketi
Üniversiteler Mah. Ihsan Dogramaci Bulv. No. 29
ODTU Teknokent Gumus Blok BK-7/B
Cankaya
Ankara
06800
Turkey**

In respect of:

The manufacture of Class IIa PC based ECG systems and ECG stress test systems with treadmills

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2003-11-12**Date: **2019-02-27**Expiry Date: **2023-11-11**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 77029

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1302	EKG Master USB Kit	Hardware and software for electrocardiography recording; to be installed and connected to a PC via USB port to use in diagnosis of cardiac diseases.
MD 1302	EKG Master USB ECG System	For electrocardiography recording to use in diagnosis of cardiac diseases
MD 1302	TM Pro Series Treadmill	Treadmill to be used for ECG Stress Testing with a Stress ECG device
MD 1302	ars-EFOR ECG Stress Test System with Treadmill	For electrocardiography recording and reporting during exercise

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